



**SUPPLEMENTARY
PARTIAL EUROPEAN SEARCH REPORT**

which under Rule 63 of the European Patent Convention EP 03 79 9822 shall be considered, for the purposes of subsequent proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	US 6 426 074 B1 (MICHEL J.L. ET AL.) 30 July 2002 (2002-07-30) * the whole document * -----	1-17	INV. A61K6/00
			TECHNICAL FIELDS SEARCHED (IPC)
			A61K
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
INCOMPLETE SEARCH			
The Search Division considers that the present application, or some or all of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for the following claims:			
Claims searched completely :			
Claims searched incompletely :			
Claims not searched :			
Reason for the limitation of the search: see sheet C			
Place of search The Hague		Date of completion of the search 21 January 2008	Examiner Moreau, Jean-Marie
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			



Although claim 16 is directed to a method of treatment of the human/animal body (Article 53(c) EPC), the search has been carried out and based on the alleged effects of the compound/composition.

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 03 79 9822

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

21-01-2008

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6426074	B1	30-07-2002	US 2003035805 A1	20-02-2003

PATENT COOPERATION TREATY

PCT

REC'D 14 MAR 2005

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

WIPO

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PP19766.002	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/29167	International filing date (day/month/year) 15 September 2003 (15.09.2003)	Priority date (day/month/year) 15 September 2002 (15.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 39/385, 39/02, 39/09, 39/00 and US Cl.: 424/197.11, 234.1, 244.1, 184.1, 236.1, 831		
Applicant CHIRON CORPORATION		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 12 April 2004 (12.04.2004)	Date of completion of this report 05 March 2005 (05.03.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized Officer Catherine Bell-Harris S. Devt, Ph.D. Telephone No. (571)272-1600	

I. Basis of the report

1. With regard to the elements of the international application:*

- the international application as originally filed.
- the description:
pages 1-31 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- the claims:
pages 32-34, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- the drawings:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in printed form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages NONE
- the claims, Nos. NONE
- the drawings, sheets/fig NONE

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/29167

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-17</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-17</u>	NO
Industrial Applicability (IA)	Claims <u>1-17</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-17 lack an inventive step under PCT Article 33(3) as being obvious over CHIRON S.P.A. in view of Michon *et al.*

CHIRON S.P.A. disclosed immunogenic compositions or vaccines comprising two or more of GBS1 through GBS689 proteins or polypeptides, including GBS80 and GBS691 proteins or polypeptides, or fragments thereof, and a streptococcal saccharide antigen. A method of making the compositions or vaccines and a method of treating an animal using the compositions or vaccines are taught. The saccharide antigen is linked to a carrier protein, such as, tetanus toxoid, diphtheria toxoid, or CRM197.

CHIRON S.P.A. does not expressly teach the streptococcal saccharide antigen in the vaccine to be of GBS serotype Ia, Ib, or III.

However, Michon *et al.* taught the use of GBS type II or III saccharide antigen covalently coupled to a bacterial carrier protein, such as, CRM197 or tetanus toxoid, in conjugate vaccines and multivalent vaccines.

The instant claims lack an inventive step because it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the streptococcal saccharide antigen conjugate in CHIRON S.P.A.'s immunogenic composition or vaccine with Michon's

GBS type II or III saccharide antigen conjugate to produce the instant invention with a reasonable expectation of success. Given Michon's teaching that such saccharide antigen conjugates are usable in multivalent vaccines, one of skill in the art would have been motivated to produce the instant invention for the expected benefit of producing a multivalent vaccine, which would advantageously provide GBS saccharide- and GBS protein- or polypeptide-specific immunity against multiple GBS serotypes.

----- NEW CITATIONS -----

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/29167

<p>A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61K 39/385, 39/02, 39/09, 39/00 US CL : 424/197.11, 234.1, 244.1, 184.1, 236.1, 831 According to International Patent Classification (IPC) or to both national classification and IPC</p>														
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) U.S. : 424/197.11, 234.1, 244.1, 184.1, 236.1, 831</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched</p> <p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet</p>														
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <thead> <tr> <th>Category *</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>Y</td> <td>WO 02/34771 A2 (CHIRON S.P.A.) 02 May 2002 (02.05.2002), pages 7, 841 and 842.</td> <td>1-17</td> </tr> <tr> <td>Y</td> <td>US 6,372,222 B1 (MICHON et al) 16 April 2002 (16.04.2002), claims and Examples.</td> <td>1-17</td> </tr> <tr> <td>Y</td> <td>US 6,426,074 B1 (MICHEL et al.) 30 July 2002 (30.06.2002), Example 14.</td> <td>1-17</td> </tr> </tbody> </table>			Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	Y	WO 02/34771 A2 (CHIRON S.P.A.) 02 May 2002 (02.05.2002), pages 7, 841 and 842.	1-17	Y	US 6,372,222 B1 (MICHON et al) 16 April 2002 (16.04.2002), claims and Examples.	1-17	Y	US 6,426,074 B1 (MICHEL et al.) 30 July 2002 (30.06.2002), Example 14.	1-17
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Y	US 6,426,074 B1 (MICHEL et al.) 30 July 2002 (30.06.2002), Example 14.	1-17												
<p><input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.</p>														
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td style="vertical-align: top;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="vertical-align: top;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> </td> </tr> </table>			<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>										
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<p>Date of the actual completion of the international search 15 April 2004 (15.04.2004)</p>		<p>Date of mailing of the international search report 02 AUG 2004</p>												
<p>Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230</p>		<p>Authorized officer <i>Joe Santa-Phelip</i> S. Devi, Ph.D. Telephone No. (703) 308-0196</p>												

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/29167

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
 2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
 3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

 4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
- Remark on Protest The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

GBS saccharide antigen species: serotype Ia; serotype Ib; and serotype III.

The claims are deemed to correspond to the species listed above in the following manner:
Claims 1 and 17.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The saccharide antigen species listed above do not share significant structural elements and immunogenic specificity.

Continuation of B. FIELDS SEARCHED Item 3:

DIALOG, WEST, EMBASE, BIOSIS, MEDLINE

GBS or group B streptococc?, (Ia or Ib or III), GBS79, GBS80 to GBS 691, inventor's name